SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dandrazol Anti-Dandruff Shampoo
Ketoconazole 20 mg/g Anti-Dandruff Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoconazole 20mg/g.

Excipient with known effect:
Sodium laureth sulfate

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Shampoo.

Clear, pink solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of dandruff.

4.2 Posology and method of administration

Adults and Adolescents aged over 12:

For use in adults and children over 12 years.

Shake the bottle well. Wash the hair or affected areas of the skin with the Shampoo. Leave in contact for 3-5 minutes before rinsing thoroughly.

Treatment of: Use twice weekly for 2-4 weeks.

Prophylaxis of: Use once every 1-2 weeks.

Do not use more than directed.

Paediatric population

Safe and effective use in infants and children under the age of 12 years has not been established.

Method of administration

For topical administration.

4.3 Contraindications

Known hypersensitivity to the active substance ketoconazole or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

To prevent a rebound effect after stopping prolonged treatment with topical corticosteroids, it is recommended to continue applying the topical corticosteroid together with ketoconazole 2% shampoo and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks.

Dandruff is associated with increased hair shedding, and this has also been

reported, although rarely, with the use of ketoconazole containing shampoos (see Undesirable Effects).

Keep out of the eyes. If the shampoo should get into the eyes, they should be bathed with cold water.

If the scalp has not cleared within 4 weeks, a doctor or pharmacist should be consulted.

This medicine contains 380 mg sodium laureth sulfate in 1 g. Sodium laureth sulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, Pregnancy and lactation

Since no ketoconazole is detected in plasma following topical administration to the scalp, pregnancy and lactation are not a contra-indication for the use of ketoconazole 2% shampoo.

There are no adequate and well-controlled studies in pregnant or lactating women. Data on a limited number of exposed pregnancies indicate no adverse effects of topical ketoconazole on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of ketoconazole. No effects on the breastfed newborn/infant are anticipated. See Pharmacokinetic properties, section 5.2.

Plasma concentrations of ketoconazole were not detectable after topical administration of ketoconazole 2% shampoo to the scalp of non-pregnant humans. Plasma levels were detected after topical administration of ketoconazole 2% shampoo on the whole body. There are no known risks associated with the use of ketoconazole 2% shampoo in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

The following table displays ADRs that have been reported with the use of Ketoconazole 2% Shampoo from either clinical trial or post marketing experiences.

The displayed frequency categories use the following convention:

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); and not known (cannot be estimated from the available clinical trial data).

Table 1: Adverse Drug Reactions

System Organ Class	**Adverse Drug Reactions**		
	Frequency Category		
	Uncommon (≥1/1,000 to <1/100)	**Rare** (≥1/10,000 and <1/1,000)	**Not Known**
Immune System disorders		Hypersensitivity	
Nervous System Disorders		Dysgeusia	
Infections and Infestations	Folliculitis		
Eye Disorders	Increased lacrimation	Eye irritation	
Skin and Subcutaneous Tissue Disorders	Alopecia Dry skin Hair texture abnormal Rash Skin burning sensation	Acne Dermatitis contact Skin disorder Skin exfoliation	Angioedema Urticaria Hair colour changes
General Disorders and Administration Site Conditions	Application site erythema Application site	Application site hypersensitivity Application site	

	irritation Application site pruritus Application site reaction	pustules	

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

In the event of accidental ingestion, only supportive measures should be carried out. In order to avoid aspiration, neither emesis nor gastric lavage should be instigated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Imidazole and triazole derivatives.

ATC Code: D01A C08 (Topical use).

Ketoconazole is an imidazole-dioxolane antimycotic, active against yeasts, including Malassezia and dermatophytes. Its broad spectrum of activity is already well known.
Ketoconazole also has a direct anti-inflammatory action independent from its antifungal activity which may contribute to symptom relief in dandruff and

seborrhoeic dermatitis.

5.2 Pharmacokinetic properties

Ketoconazole does not appear to be appreciably absorbed systemically following topical application of a 2% shampoo to skin. Ketoconazole was not detected in plasma of patients receiving topical application of 2% shampoo 4-10 times weekly for 6 months, or in patients using 2% shampoo 2-3 times weekly for an average of 16 months. Following a single topical application, substantial amounts of the drug were detected in hair 12 hours after application; however only 5% of the applied ketoconazole was detected in hair keratin. Following repeated (twice weekly for 2 months) application, 20% of the applied dose was detected in hair keratin.

5.3 Preclinical safety data

In vitro studies using ketoconazole in a microbial system (i.e., Ames test) have not shown the drug to be mutagenic. In addition, there was no evidence of mutagenicity in any stage of germ cell development in a dominant lethal mutation test in mice who received single oral doses of ketoconazole as high as 80 mg/kg. There was no evidence of carcinogenicity in a long-term feeding study in mice and rats. Hepatotoxicity featured prominently in high dose toxicology studies in animals and occurs in about 1 in 10,000 patients.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium laureth sulfate
Disodium laureth sulfosuccinate
PEG-120 Methyl glucose dioleate
PEG-7-Glyceryl Cocoate
Imidurea

Lauryldimonium hydroxypropyl hydrolysed collagen
Cocamide DEA
Sodium hydroxide
Sodium chloride
Erythrosine C.I. 45430 (E127)
Hydrochloric acid concentrated
Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25 °C

6.5 Nature and contents of container

White opaque HDPE bottle with PP closure.
Pack sizes 60, 80, 100ml.

6.6 Special precautions for disposal

No special instructions

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited
Key House
Sarum Hill, Basingstoke
RG21 8SR
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0876

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/01/2009

10 DATE OF REVISION OF THE TEXT

06/06/2024